EXHIBIT G

American National Standard

ANSI/AAMI/ISO 14971:2000
(Revision of ANSI/AAMI/ISO 14971-1:1998)

Medical devices—Application of risk management to medical devices

Approved 16 October 2000 by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute

Abstract: This American National Standard specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories (including *in vitro* diagnostic medical devices), estimate and evaluate the risks, control these risks, and monitor the effectiveness of the control.

Keywords: risk, hazard, risk management, risk analysis, risk assessment, medical devices, medical equipment

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by International designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI, therefore this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI VP20:1994	Major technical variations
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x [1)]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical

1) FDIS approved; being prepared for publication.

International designation	U.S. designation	Equivalency
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO TS 15843:2000	AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO 14971, second edition, as an American National Standard was initiated by the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices, which also serves as a U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Application of Risk Management to Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210-IEC/SC 62A JWG1-RM) played an active role in developing the ISO Standard.

The **AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices** has the following members:

Chair:	Robert C. Flink
Members:	Robert C. Flink, Medtronic, Inc.
	Leighton Hansel, U.S. Food and Drug Administration
	Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.
	Harvey Rudolph, PhD, Underwriters Laboratories, Inc.
	Kimberly A. Trautman, U.S. Food and Drug Administration
Alternate:	Charles B. Sidebottom, Medtronic, Inc.

The **AAMI Application of Risk Management to Medical Devices Working Group** has the following members:

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Members:	Steve B. Binion, Baxter Healthcare
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	Robert Casson, Pfizer Inc. Medical Technology Group
	Roger Dabbah, U.S. Pharmacopeial
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	J. Glenn George, Stat-A-Matrix
	Nancy George, Software Quality Management, Inc.
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	Paul McDaniel, Hill Rom Co.
	Allan Miyoshi, St. Jude Medical, Inc.
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	Mike Rahn, Griffith Micro Science, Inc.

Mark N. Smith, Getinge/Castle, Inc.
Byron Tart, U.S. Food and Drug Administration

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO 14971:2000

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this International Standard.

ISO 14971 was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62A, *Common aspects of electrical equipment in medical practice*, to fill a need for an international standard on risk management to help determine the probability of possible consequences of a postulated event relating to the application of a medical device. U.S. participation in ISO/TC 210 is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation on behalf of the American National Standards Institute. The United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international documents as much as possible. Upon review of ISO 14971, the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices and the AAMI Application of Risk Management to Medical Devices Working Group decided to adopt ISO 14971 verbatim as a revision of ANSI/AAMI/ISO 14971-1:1998.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency to the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page x, this American National Standard is identical to ISO 14971:2000.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

In the field of risk management for medical devices, Technical Committee ISO/TC 210 and IEC/SC 62A have established a joint working group, JWG 1, *Application of risk management to medical devices*.

International Standard ISO 14971 was prepared by ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

Requirements concerning the risk analysis component of the risk management process were developed first and published as ISO 14971-1:1998, with the intention that the requirements for risk evaluation, risk control, and post-production information evaluation could be covered in additional part(s), but all the requirements have now been incorporated into this International Standard.

This first edition of ISO 14971 cancels and replaces ISO 14971-1:1998.

For purposes of future IEC maintenance, Subcommittee 62A has decided that this publication remains valid until 2004. At this date, Subcommittee 62A, in consultation with ISO/TC 210, will decide whether the publication will be

— reconfirmed,

— withdrawn,

— replaced by a revised edition, or

— amended.

Annexes A to G of this International Standard are for information only.

Introduction

This International Standard should be regarded as a framework for effective management by the manufacturer of the risks associated with the use of medical devices. The requirements that it contains provide a framework within which experience, insight, and judgment are applied systematically to manage these risks.

As a general concept, activities in which an individual, organization, or government is involved can expose those or other stakeholders to hazards which may cause loss or damage of something they value. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and on the detriment that might be suffered on exposure to a hazard.

It is accepted that the concept of risk has two components:

a) the probability of occurrence of harm, that is, how often the harm may occur;

b) the consequences of that harm, that is, how severe it might be.

The acceptability of a risk to a stakeholder is influenced by these components and by the stakeholder's perception of the risk.

These concepts are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients, and members of the public.

All stakeholders need to understand that the use of a medical device entails some degree of risk. Factors affecting each stakeholder's perception of the risks include the socioeconomic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a risk is perceived also takes into account, for example, whether exposure to the risk seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society. The decision to embark upon a clinical procedure utilizing a medical device requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgments should take into account the intended use/intended purpose, performance, and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgments may be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.

As one of the stakeholders, the manufacturer should make judgments relating to safety of a medical device, including the acceptability of risks, taking into account the generally accepted state of the art, in order to determine the probable suitability of a medical device to be placed on the market for its intended use/intended purpose. This International Standard specifies a procedure by which the manufacturer of a medical device can identify hazards associated with a medical device and its accessories, estimate and evaluate the risks associated with those hazards, control those risks, and monitor the effectiveness of that control.

For any particular medical device, other International Standards may require the application of specific methods for controlling risk.

Medical devices—Application of risk management to medical devices

1 Scope

This International Standard specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories, including *in vitro* diagnostic medical devices, estimate and evaluate the risks, control these risks, and monitor the effectiveness of the control.

The requirements of this International Standard are applicable to all stages of the life cycle of a medical device.

This International Standard does not apply to clinical judgments relating to the use of a medical device.

It does not specify acceptable risk levels.

This International Standard does not require that the manufacturer has a formal quality system in place. However, risk management can be an integral part of a quality system (see, for example, Table G.1).

2 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply:

2.1 accompanying document: Document accompanying a medical device, or an accessory, and containing important information for the user, operator, installer, or assembler of the medical device, particularly regarding safety.

NOTE—Based on IEC 60601-1:1988, definition 2.1.4.

2.2 harm: Physical injury or damage to the health of people, or damage to property or the environment.

[ISO/IEC Guide 51:1999, definition 3.1]

2.3 hazard: Potential source of harm.

[ISO/IEC Guide 51:1999, definition 3.5]

2.4 hazardous situation: Circumstance in which people, property, or the environment are exposed to one or more hazard(s).

[ISO/IEC Guide 51:1999, definition 3.6]

2.5 intended use/intended purpose: Use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacturer.

2.6 manufacturer: Natural or legal person with responsibility for the design, manufacture, packaging, or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

2.7 medical device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

— diagnosis, prevention, monitoring, treatment, or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,

— investigation, replacement, or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its function by such means.

[ISO 13485:1996, definition 3.1]

2.8 objective evidence: Information which can be proven true, based on facts obtained through observation, measurement, test, or other means.

[ISO 8402:1994, definition 2.19]

2.9 procedure: Specific way to perform an activity.

[ISO 8402:1994, definition 1.3]

2.10 process: Set of interrelated resources and activities which transform inputs into outputs.

[ISO 8402:1994, definition 1.2]

2.11 record: Document which furnishes objective evidence of activities performed or results achieved.

[ISO 8402:1994, definition 3.15]

2.12 residual risk: Risk remaining after protective measures have been taken.

[ISO/IEC Guide 51:1999, definition 3.9]

2.13 risk: Combination of the probability of occurrence of harm and the severity of that harm.

[ISO/IEC Guide 51:1999, definition 3.2]

2.14 risk analysis: Systematic use of available information to identify hazards and to estimate the risk.

[ISO/IEC Guide 51:1999, definition 3.10]

2.15 risk assessment: Overall process comprising a risk analysis and a risk evaluation.

[ISO/IEC Guide 51:1999, definition 3.12]

2.16 risk control: Process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.

2.17 risk evaluation: Judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.

NOTE—Based on ISO/IEC Guide 51:1999, definitions 3.11 and 3.7.

2.18 risk management: Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, and controlling risk.

2.19 risk management file: Set of records and other documents, not necessarily contiguous, that are produced by a risk management process.

2.20 safety: Freedom from unacceptable risk.

[ISO/IEC Guide 51:1999, definition 3.1]

2.21 severity: Measure of the possible consequences of a hazard.

2.22 verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

NOTE—In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.

[ISO 8402:1994, definition 2.17]

3 General requirements for risk management

3.1 National or regional regulatory requirements

Because of the wide variety of medical devices covered by this International Standard and the different national or regional regulatory requirements covering those devices, the requirements given in 3.3 and 3.4 apply as appropriate.

3.2 Risk management process

The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the control. This process shall be documented and shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control; and

— post-production information.

Where a documented product design/development process exists, it shall incorporate the appropriate parts of the risk management process.

NOTE 1—A documented product design/development process can be used to deal with safety in a systematic manner, in particular to enable the early identification of hazards in complex systems and environments.

NOTE 2—A schematic representation of the risk management process is shown in Figure 1.

NOTE 3—See the bibliography.

Compliance is checked by inspection of the risk management file.

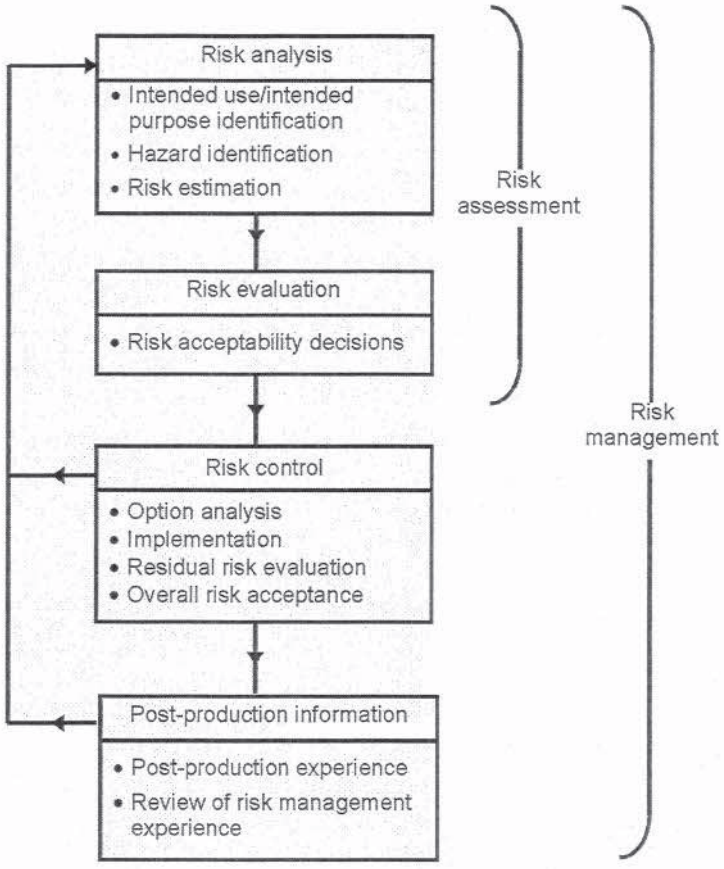

Figure 1—Schematic representation of the risk management process

3.3 Management responsibilities

The manufacturer shall

a) define the policy for determining acceptable risk, taking into account relevant International Standards and national or regional regulations,

b) ensure the provision of adequate resources,

c) ensure the assignment of trained personnel (see 3.4) for management, performance of work and assessment activities, and

d) review the results of risk management activities at defined intervals to ensure continuing suitability and the effectiveness of the risk management process.

The above shall be documented in the risk management file.

Compliance is checked by inspection of the risk management file.

3.4 Qualification of personnel

The manufacturer shall ensure that those performing risk management tasks include persons with knowledge and experience appropriate to the tasks assigned to them. This shall include, where appropriate, knowledge and experience of the medical device and its use and risk management techniques. Records of the appropriate qualifications shall be maintained.

Compliance is checked by inspection of the appropriate records.

3.5 Risk management plan

For the particular medical device or accessory being considered, the manufacturer shall prepare a risk management plan in accordance with the risk management process. The risk management plan shall be part of the risk management file.

This plan shall include the following:

a) The scope of the plan, identifying and describing the medical device and the life cycle phases for which the plan is applicable;

b) a verification plan;

c) allocation of responsibilities;

d) requirements for review of risk management activities; and

e) criteria for risk acceptability.

NOTE—The criteria for risk acceptability will do much to determine the ultimate effectiveness of the risk management process. Refer to annex E for guidance on establishing such criteria.

If the plan changes during the life cycle of the medical device, a record of the changes shall be maintained in the risk management file.

Compliance is checked by inspection of the risk management file.

3.6 Risk management file

For the particular medical device or accessory being considered, the results of all risk management activities shall be recorded and maintained in the risk management file.

NOTE 1—The records and other documents that make up the risk management file can form part of other documents and files required, for example, by a manufacturer's quality management system.

NOTE 2—The risk management file need not physically contain all the documents relating to this International Standard. However, it should contain at least references or pointers to all required documentation. The manufacturer should be able to assemble the information referenced in the risk management file in a timely fashion.

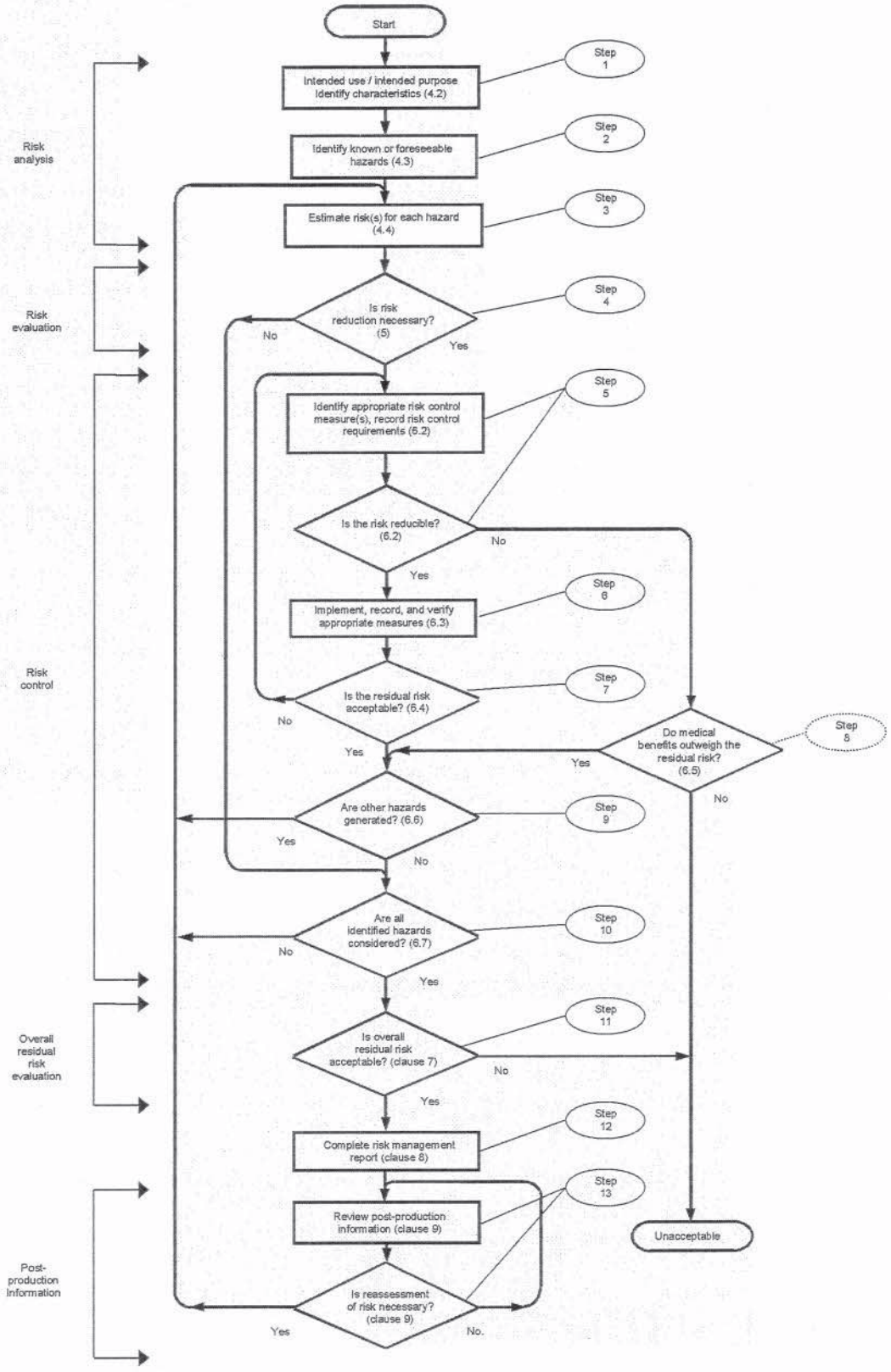

Figure 2—Overview of risk management activities as applied to medical devices

4 Risk analysis (Steps 1, 2, and 3 of Figure 2)

4.1 Risk analysis procedure

Risk analysis, as described in 4.2 to 4.4, shall be performed, and the conduct and results of the risk analysis shall be recorded in the risk management file.

NOTE—If a risk analysis is available for a similar medical device, it may be used as a reference provided it can be demonstrated that the processes are similar or that the changes that have been made will not introduce significant differences in results. This should be based on a systematic evaluation of the changes and the ways they can influence the various hazards present.

In addition to the records required in 4.2 to 4.4, the documentation of the conduct and results of the risk analysis shall include at least the following:

a) a description and identification of the medical device or accessory that was analyzed;

b) identification of the person(s) and organization which carried out the risk analysis;

c) date of the analysis.

Compliance is checked by inspection of the risk management file.

4.2 Intended use/intended purpose and identification of characteristics related to the safety of the medical device (Step 1)

For the particular medical device or accessory being considered, the manufacturer shall describe the intended use/intended purpose and any reasonably foreseeable misuse. The manufacturer shall list all those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits (see Note 1). These records shall be maintained in the risk management file.

NOTE 1—Annex A contains questions that can serve as a useful guide in drawing up such a list.

NOTE 2—Additional guidance on risk analysis techniques for *in vitro* diagnostic medical devices is given in annex B.

NOTE 3—Additional guidance on risk analysis techniques for toxicological hazards is given in annex C.

Compliance is checked by inspection of the risk management file.

4.3 Identification of known or foreseeable hazards (Step 2)

The manufacturer shall compile a list of known or foreseeable hazards associated with the medical device in both normal and fault conditions. Previously recognized hazards shall be identified. This list shall be maintained in the risk management file.

Foreseeable sequences of events that may result in a hazardous situation shall be considered and recorded.

NOTE 1—The examples of possible hazards listed in annex D and in clause B.2 for *in vitro* diagnostic medical devices can be used as a memory aid.

NOTE 2—To identify hazards not previously recognized, systematic methods covering the specific situation can be used (see annex F).

Compliance is checked by inspection of the risk management file.

4.4 Estimation of the risk(s) for each hazard (Step 3)

For each identified hazard, the risk(s) in both normal and fault conditions shall be estimated using available information or data. For hazards for which the probability of the occurrence of harm cannot be estimated, a listing of the possible consequences of the hazard shall be prepared. The estimate of the risk(s) shall be recorded in the risk management file.

Any system used for qualitative or quantitative categorization of probability estimates or severity levels shall be recorded in the risk management file.

NOTE 1—Risk estimation incorporates an analysis of the probability of occurrence and the consequences. Depending on the area of application, only certain elements of the risk estimation process may need to be considered. For example, in some instances it will not be necessary to go beyond an initial hazard and consequence analysis.

NOTE 2—Risk estimation can be quantitative or qualitative. Methods of risk estimation, including those resulting from systematic faults, are described in annex E. Clause B.3 gives information useful for estimating risks for *in vitro* diagnostic medical devices.

NOTE 3—Some techniques that can be used for analysis of risks are described in annex F.

NOTE 4—Information or data for estimating risks can be obtained, for example, from

— published standards,

— scientific technical data,

— field data from similar medical devices already in use including published reported incidents,

— usability tests employing typical users,

— clinical evidence,

— results of appropriate investigations,

— expert opinion,

— external quality assessment schemes.

Compliance is checked by inspection of the risk management file.

5 Risk evaluation (Step 4)

For each identified hazard, the manufacturer shall decide, using the criteria defined in the risk management plan, whether the estimated risk(s) is so low that risk reduction need not be pursued. In this case, the requirements given in 6.2 to 6.6 do not apply for this hazard (i.e., proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.

NOTE 1—Guidance for deciding on risk acceptability is given in clause E.3.

NOTE 2—Application of relevant standards as part of the medical device design criteria might constitute risk control activities, thus necessitating application of the requirements given in 6.3 to 6.6.

Compliance is checked by inspection of the risk management file.

6 Risk control (Steps 5 to 10)

6.1 Risk reduction

When risk reduction is required, the manufacturer shall follow the process specified in 6.2 to 6.7 to control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable.

6.2 Option analysis (Step 5)

The manufacturer shall identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level. Risk control shall consist of an integrated approach in which the manufacturer shall use one or more of the following in the priority order listed:

a) inherent safety by design;

b) protective measures in the medical device itself or in the manufacturing process;

c) information for safety.

NOTE 1—Measures of risk control can reduce the severity of the potential harm or reduce the probability of occurrence of the harm, or both.

NOTE 2—Technical standards address inherent, protective, and descriptive safety for many medical devices. These should be consulted as part of the risk management process. See also annex G.

The risk control measures selected shall be recorded in the risk management file.

If, during option analysis, the manufacturer determines that further risk reduction is impractical, the manufacturer shall conduct a risk/benefit analysis of the residual risk (see 6.5); otherwise, the manufacturer shall proceed to implement the selected risk control measures.

Compliance is checked by inspection of the risk management file.